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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,466

10/14/2003

Nurith Kum

492692000610

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25226 7590 03/21/2006

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EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/686,466

Applicant(s)

KURN, NURITH

Examiner

Teresa E. Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-30,32,33,35,37-40,45-53,56-60 and 64-67 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 17-30,32,33,35,37-40,45-53,56-60 and 64-67 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 17-30, 32, 33, 35, 37-40, 45-53, 66 and 67, drawn to a method of generating multiple copies of a nucleic acid sequence using transcription and amplification, classified in class 435, subclass 91.2, for example.
 - II. Claims 56-60, 64 and 65, drawn to a system and a kit comprising a primer, an RNA-dependent DNA polymerase, an enzyme that cleaves RNA from RNA/DNA hybrid and an RNA polymerase, classified in class 536, subclass 23.4, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the kit of Group II can be used in an entirely different method, such as in vitro transcription-translation system rather than in the method of Group I.

Searching the inventions of Groups I and II together would impose serious search burden. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the system comprising a primer and polymerases and the method of amplification using the system are not coextensive. Prior art which teaches a system of Group II would not necessarily be applicable to the method of Group

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I, as many different methods of amplification use the system of Group II. Moreover, even if the system product were known, the method of using the product may be novel and unobvious in view of the preamble or active steps.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.

Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86

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(March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. This application contains claims directed to the following patentably distinct species:

GROUP I

Species of the target polynucleotide

- A) target polynucleotide is DNA (claim 21),
- B) target polynucleotide is RNA (claims 22, 27),.

Species of the first and second primers

- C) the first and second primers are the same (claim 23),
- D) the first and second primers are different (claim 24),
- E) the first and second primers hybridize to different complementary sequences (claim 25).

Species of the propromoter oligonucleotide

- F) propromoter oligonucleotide is a TSO (claim 28),
- G) propromoter oligonucleotide is a PTO (claim 29).

Species of the polymerases

- H) the DNA polymerase is a DNA-dependent DNA polymerase and the DNA-dependent DNA polymerase and the RNA-dependent DNA polymerase are one enzyme (claim 32),

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I) the RNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 33),

J) the DNA polymerase is a DNA-dependent DNA polymerase, and the DNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 35),

K) the DNA polymerase is a DNA-dependent DNA polymerase, and the DNA-dependent DNA polymerase, the RNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 37).

Species of methods incorporating the method of claim 17

L) a method of sequencing nucleic acids (claims 38, 39 and 66),

M) a method of detecting a mutation in a target polynucleotide (claim 40),

N) a method of producing a microarray (claim 44),

O) a method of analyzing a sequence of interest (claims 46-51),

P) a method of determining a gene expression profile (claims 52, 53),

Q) a method of detecting a presence of nucleic acid sequence of interest in the sample (claim 67).

GROUP II

Species of the polymerases

H) the DNA-dependent DNA polymerase and the RNA-dependent DNA polymerase are one enzyme (claim 57),

I) the RNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 59),

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J) the DNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 58),

K) the DNA-dependent DNA polymerase, the RNA-dependent DNA polymerase and enzyme that cleaves RNA from an RNA/DNA hybrid are the same enzyme (claim 60).

The species are independent or distinct because they are drawn to entities with different structures and functions, as well as to different methods starting with the same set of steps.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 17 and 56 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and

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specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TERESA STRZELECKA
PATENT EXAMINER

Teresa Strzelecka

3/17/06